



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/675,705 | 09/30/2003 | Mark S. Ortiz | END5102.0515147 | 6304 |

7590 05/04/2007
FROST BROWN TODD LLC
2200 PNC Center
201 E. Fifth Street
Cincinnati, OH 45202-4182

| |
|----------|
| EXAMINER |
|----------|

POUS, NATALIE R

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

05/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/675,705 | ORTIZ, MARK S. | |
| | Examiner | Art Unit | |
| | Natalie Pous | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8-12 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-12 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/7/06, 10/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/22/07 has been entered.

Claim Objections

Claims 3 and 4 are objected to because of the following informalities: claims 3 and 4 depend from canceled claim 2, it is inferred that the proper dependency for claims 3 and 4 is from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3731

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 8, 9, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yencho et al. (US 7004949) in view of Huebsch et al. (US 5853422). Yencho teaches an anastomosis device capable of forming an anastomosis between two gastrointestinal tissue lumens of a gastrointestinal tract and capable of passage of gastrointestinal contents there through, comprising:

- A proximal ring (112)
- A distal ring (113)
- A plurality of proximal arms (124) each attached to the proximal ring at one end and having a distally directed other end (fig. 12)
- A plurality of distal arms (123) attached to the distal ring at one and having a proximally directed other end (fig. 12)
- A center ring (111) coupling the proximal end of each distal arm to the distal end of each proximal arm;
- Wherein the anastomosis device forms a cylindrical shape when unactuated (fig. 12), and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape (fig. 20),
- And when the anastomosis device is in either the unactuated (fig. 12) and the actuated (fig. 20) position, a substantially unobstructed passageway (fig. 16) is provided thorough the anastomosis device (110), the passageway extending from a proximal end of the proximal ring to a distal end of the distal ring and wherein

Art Unit: 3731

when the passageway passes through a ring, the passageway has substantially the same diameter as the ring (fig. 16)

- Wherein the proximal and distal arms are radially aligned (fig. 14)
- wherein the device is formed from a formable material wherein when the device is moved from a first shape to a second shape, the material permanently deforms into the second shape (fig. 20)
- wherein the proximal and distal arms include a hinge (121)

Yencho fails to teach a latching mechanism operably configured to lock at a reduced longitudinal spacing two selected from a group consisting of the proximal ring, the distal ring, and the center ring comprising at least one interiorly disposed hook extending within the passageway and comprising an interference fit formed between the rings. Huebsch teaches a device comprising proximal, center and distal rings connected by proximal and distal arms, wherein in the unactuated position comprises a cylindrical shape, and in the actuated position comprises a rivet shape, and is intended for securement to tissue, wherein the device comprises a latching mechanism (242) and the center ring comprises at least one interiorly disposed hook (240) extending within the passageway and comprising an interference fit formed between the rings in order to securely and mechanically lock the device in its actuated configuration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yencho with a locking mechanism as taught by Huebsch in order to securely and mechanically lock the device in its actuated configuration.

Claim 4, is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch in view of Corcoran (US 6379368). The combination of Yencho and Huebsch teaches all limitations of preceding dependent claim 1, but fails to teach wherein the proximal arms are radially staggered with the distal arms. Corcoran teaches a device for placement on opposing sides of tissue, wherein the proximal extending tissue contacting portions are staggered with respect to the distal extending tissue contacting portions as seen in fig. 1 in order to allow the device to be used in a variety of physical anomalies of a variety of sizes and shapes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with staggered tissue contacting portions on the proximal and distal sides in order to allow the device to be used in a variety of physical anomalies of a variety of sizes and shapes.

Claim 5, is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch in view of Berg (US 6712836).

Regarding the limitations wherein device comprises a radiopaque material, the combination of Yencho and Huebsch teaches all limitations of preceding dependent claim 1 as previously described, but fails to disclose wherein the device comprises a radiopaque target material. Berg teaches a device comprising a radiopaque material in order to view the device during deployment using imaging techniques to determine the device is deployed at the proper location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with a radiopaque material as taught by Berg in order to view the device

during deployment using imaging techniques to determine the device is deployed at the proper location.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch in view of Barra et al. (US 5843088). The combination of Yencho and Huebsch teaches all limitations of preceding dependent claims 1 and 11 as previously described, but fails to disclose wherein a pad is outwardly disposed on each inner arm segment. Barra teaches a device wherein pads (6) are disposed on the portion touching tissue in order to gently rest the device on the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with pads on the portion of the device touching tissue in order to allow the device to gently rest on the tissue.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch as applied to claim 1 above, and further in view of Allen et al. (US 5649938). The combination of Yencho and Huebsch teaches all limitations of preceding dependent claim 1 but fails to teach wherein the anastomosis device consists of biofragmentable material. Allen teaches the use of an anastomosis device comprising biofragmentable material in order to provide a device that stays in place until healing occurs, and is then eliminated from the body in small harmless fragments. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with a biofragmentable material as taught by Allen in order to provide a device that stays in

place until healing occurs, and is then eliminated from the body in small harmless fragments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
4/25/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
